

Message Text

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PAGE 01 STATE 066324
ORIGIN HEW-06

INFO OCT-01 EA-12 ISO-00 OES-07 /026 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:VB
APPROVED BY OES/ENP/EN: WJWALSH, III
DHEW/PHS/OASH/OIH: REVANS
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-----120909 151740Z /47

P 151551Z MAR 78
FM SECSTATE WASHDC
TO AMEMBASSY CANBERRA PRIORITY

UNCLAS STATE 066324

E.O. 11652:N/A

TAGS: TBIO, AS

SUBJECT: REQUEST FOR CONFIRMATION ON FALSIFICATION OF
CLINICAL TRIALS ON DRUGS

REFERENCE: CANBERRA 1726

1. FDA CONFIRMS THAT DR. DONALD KENNEDY, COMMISSIONER, FOOD AND DRUG ADMINISTRATION IN TESTIMONY BEFORE U.S. SENATE SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH COMMITTEE ON HUMAN RESOURCES STATED THAT "WE ARE IN THE PROCESS OF CONDUCTING 26 (FOR CAUSE) INSPECTIONS. ALTHOUGH WE HAVE NOT COMPLETED OUR EVALUATIONS OF ALL INSPECTIONS TO DATE, I WOULD LIKE TO SHARE SOME OF OUR FINDINGS. DEPENDING ON YOUR PERSPECTIVE, THEY COULD BE DESCRIBED AS "UNUSUAL", "HORRIBLE", OR "INCONCEIVABLE"."

2. DR. KENNEDY STATED (PARAPHRASED) THAT THERE WERE CASES OF (A) CASE REPORTS ON FICTITIOUS SUBJECTS AND ON SUBJECTS WHO WERE NEVER ADMINISTERED THE INVESTIGATIONAL DRUGS.
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(B) CASE REPORTS CONTAINING THE RESULTS OF CLINICAL LABORATORY TESTS WHICH WERE NOT ACTUALLY PERFORMED. (C) FALSE REPRESENTATION OF PATIENT DIAGNOSIS AND DEMOGRAPHIC DATA.

(D) MISREPRESENTATION OF PATIENT DIAGNOSIS AND DEMOGRAPHIC DATA. (E) CONSENT OF SUBJECT NOT OBTAINED. (F) DRUG DOSES GIVEN IN EXCESS OF PROTOCOL LIMITATIONS. (G) DRUGS

GIVEN TO INAPPROPRIATE SUBJECTS. (H) SERIAL USE OF
INVESTIGATIONAL DRUGS TO EXCLUSION OF ACCEPTED THERAPY.
(I) ADMINISTRATION TO GIVE SUBJECT OF TWO (2) OR MORE
INVESTIGATIONAL DRUGS AT SAME TIME, ETC.

3. FULL TEXT OF STATEMENT BEING AIRMAILED TO EMBASSY FOR
ITS INFORMATION AND USE. VANCE

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 jan 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: DRUGS, DOCUMENTS, TRIALS, INFORMATION CONTROL, LABORATORIES
Control Number: n/a
Copy: SINGLE
Draft Date: 15 mar 1978
Decaption Date: 01 jan 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
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Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:VB
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Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D780115-0618
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1978/newtext/t19780364/aaaaccla.tel
Line Count: 69
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 183fcec6-c288-dd11-92da-001cc4696bcc
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Original Classification: UNCLASSIFIED
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Original Previous Classification: n/a
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TAGS: TBIO, AS
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Review Markings:
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